REMARKS

Claims 1-6, 8-10, and 12-24 are pending in this application. Claims 7 and 11 were canceled previously.

Claims 1 and 12 currently have been amended to recite additionally: "...with a needle..." Support for this amendment may be found, for example, in paragraph [0044] of the instant U.S. Published Application. As examples, U.S. Patents 5,670,484, 6,458,365 and 5,714, 468 which were incorporated by reference (*see* paragraph [0111]) in [0044] provide that botulinum toxin may be administered by a needle. Specifically, col. 6, lines 12-15 of the '484 patent states: "Preferably, the injection will be provided to the subcutaneous or subdermal region beneath the lesion by inserting the needle ..." (Emphasis added).

Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. MPEP § 2163.07(b). The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. *Id.* Replacing the identified material incorporated by reference with another is not new matter. *Id.*

Claims 25-27 have been canceled herein without disclaimer or prejudice and solely to expedite prosecution. Applicants may pursue the subject matter of canceled claims 25-27 in one or more future applications.

Rejections under 35 USC § 102

Claims 1-6, 8-10, 12-21, and 25-27 are rejected under 35 USC 102(e) as anticipated by U.S. Patent Publication 2004/0087893 ("Kwon"), as evidenced by Allergan (pages 1-4, http://www.allergan.com/download/BotoxPL.pdf, accessed on March 22, 2007).

Applicant respectfully traverses.

The law is clear that in order to anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clark Corp.*, 218 USPQ2d 781, 789 (Fed. Cir. 1983, cert denied, 465 U.S. 1026 (1984)).

Kwon does not disclose delivery of botulinum toxin with a needle.

Kwon does not identically disclose administration of botulinum toxin with a needle as now claimed. Kwon stated in paragraph [0077] that in "contrast to conventional hollow needle technologies, the SSP system includes a solid matrix of dissolvable (including meltable) or biodegradable material that optionally holds one or more selected drugs and is formed into one or more perforators." (Emphasis added). Further, during prosecution, Kwon responded to an Office action dated June 1, 2004 with an amendment submitted on August 27, 2004. The submitted remarks therein clearly show that Kwon's disclosure excludes delivery of botulinum toxin with a needle:

> Neither Melone or Eicher teach or suggest an array of **dissolvable perforators** as claimed. As explained throughout the present application, the salient feature of applicant's invention is that the perforators used to pierce or otherwise make channels in the skin are **themselves dissolvable**. The matrix used to form the perforators is made of the drug to be delivered and/or of a soluble material that quickly dissolves after insertion into the skin. This technology is quite distinct from hollow needle technologies and the like, that use microneedles and other injection devices made from materials such as metals and polymers that do not dissolve upon contact with the skin. For example, Melone uses metal plates with

> needlelike projections that are coated with the desired substance. There is no disclosure in Melone regarding dissolvable perforators. Similarly, Eicher uses micro-pins with capillary openings to deliver the active substance. Although Eicher states that the pins can be made from biodegradable polymers, the biodegradable polymers described do not dissolve within seconds or hours as claimed. Moreover, Eicher's micro-pins do not include a drug incorporated therein. Thus, Melone and Eicher do not teach each and every element of the claimed invention and therefore cannot anticipate the present claims. (Emphasis Original, Page 10, ¶3, Kwon's Amendment dated August 27, 2004).
>
> However, as with Melone and Eicher above, Lastovich nowhere describes dissolvable **perforators** as claimed. Rather, Lastonvich uses microneedles or the like to perforate the skin and drug is either delivered through a central channel in the needle or is coated onto the outside of the needle. (Emphasis Original, Page 11, ¶1, Kwon's Amendment dated August 27, 2004).

As one of ordinary skill in the art can plainly see from the above excerpt and also from its own disclosure, Kwon not only fails to anticipate the present claims by falling short of identical disclosure but actively takes the step of excluding the currently introduced element: "...with a needle..." Thus, Kwon does not teach each and every element of the present claims.

In view of the foregoing, Applicant respectfully submits that Kwon does not anticipate the present claims. Therefore, Applicant requests withdrawal of the rejection under 35 USC § 102(e) by Kwon (US 2004/0087893).

Kwon's matrix to be delivered is a solid.

The Office dismissed the limitation in present claims 1 and 12 which require that a "solution is administered by intradermal or subdermal injection." This was done by asserting that "While the Kwon reference discloses the use of a SSP (which uses needles, blades or other perforators), at the point of administration the botulinum toxin is in a solution form, which is indicative of a liquid solution. Although Kwon uses a SSP,

perforators by definition (i.e. to pierce or penetrate) meet the limitations of the instant claims." (Instant Office action, page 5, ¶3).

Applicant respectfully disagrees.

Kwon does not identically teach the presently disclosed claims because its delivery system must include a perforator which is "quite distinct from hollow needle technologies and the like" (*Id.*) Therefore, Kwon's system is not identical to the presently claimed invention which utilizes a needle to deliver a liquid solution comprising a botulinum toxin.

Further, as Kwon made clear during its prosecution, the "matrix used to form the perforators is made of the drug to be delivered and/or of a soluble material that quickly dissolves after insertion into the skin." *Id.* There is no need to dissolve a liquid solution. Dissolving is needed because it is a solid before the matrix is placed under the skin. In contrast, Applicants claims 1 and 2 delivers liquid solution comprising botulinum toxin by intradermal or subdermal injection. Kwon may have recited the word "needles" in paragraph [0010] of its disclosure. But such a recitation of "needles" in Kwon should be considered in context with for example paragraph [0004], [0007], and [0008] of the same disclosure, and its prosecution history which specifically excluded needles.

Kwon does not teach or suggest delivery of a non-paralytic amount of botulinum toxin

As Applicant show below, support exists for claim 1 and 12's requirement that the botulinum toxin administered is less than the amount used to paralyze a muscle.

Kwon in paragraph [0077] stated that: "Another area of applications is cosmeceutical. An SSP system including a patch can deliver botox toxin or hydroxyacid more efficiently and safely to remove or reduce wrinkle formation and skin aging."

Kwon makes no distinction as to whether "botox toxin" is to be administered in non-paralytic or paralytic amounts. Thus, claim 1 and 12's requirement that the

botulinum toxin administered is less than the amount used to paralyze a muscle is not identically disclosed.

Further, Kwon's disclosure does not necessarily lead to delivery of botulinum toxin in less than the amount used to paralyze a muscle. It is very possible that Kwon's delivery of botulinum toxin would paralyze a muscle. This is evidenced by the fact that Kwon specifically mentions wrinkle treatment. It is well-known that muscle paralysis may occur when injecting botulinum toxin to treat wrinkles since the treatment involves relaxing the muscles underlying the wrinkles. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. An applicant may be required to prove that the subject matter to be in the prior art does not possess characteristics relied upon, where an Examiner has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art. However, the Examiner must provide some evidence or scientific reasoning to establish the reasonableness of the Examiner's belief that the functional limitation is an inherent characteristic of the prior art before the application can be put through this burdensome task. *Ex parte Skinner*, 2 USPQ2d 1788 (BPAI 1986).

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 1-6, 8-10, 12-21 and 25-27 under 35 USC § 102(e) as being anticipated by Kwon.

Rejections under 35 USC § 112 ¶¶ 1 and 2

Claims 1-6, 8-10 and 12-27 are rejected under 35 USC § 112, ¶1, as failing to comply with the written description requirement because of the recited limitation "less than the amount used to paralyze a muscle."

First, Applicant refers the Office to paragraph [0061] of the instant disclosure (U.S. Published Application) whether there is literal support for this limitation: "The dose

of a Clostridial toxin used according to the present invention is less than the amount of toxin that would be used to paralyze a muscle, since the intent of a method according to the present invention is not to paralyze a muscle but to treat a skin disorder." (Emphasis added).

According to the Office, adequate support is not present because the specification is silent with regard to how to determine what an effective amount equate to that is less than the amount used to paralyze a muscle. Applicant submits that this requirement imposed by the Office goes beyond what is required by the MPEP and relevant case law. This is because there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). Especially when virtually verbatim literal support exists in the specification as filed, the Office bears a heavy burden of overcoming the strong presumption of adequate written description. One of ordinary skill in the art would be able to determine what amount of botulinum toxin to be administered is a non-paralyzing amount for a muscle.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection under 35 USC § 112, ¶1 of claims 1-6, 8-10 and 12-27.

Claims 1-6, 8-10 and 12-27 are rejected under 35 USC § 112, ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant respectfully traverses.

The Office again finds issue with the recited limitation "less than the amount used to paralyze a muscle" this time as being indefinite. According to the Office, it is unclear what amount is "less than the amount used to paralyze a muscle." The implication is that if the Office were to be able to determine this amount it would not be "impossible to determine the metes and bounds of the claimed invention." (Instant Office action, Page 10, Item 5).

Applicant submits, as argued above, one of ordinary skill in the art would be able to determine what amount of botulinum toxin is less than the amount used to paralyze a muscle. Requiring the Applicant to specify what these amount are exceeds the requirement for definiteness of a claim. Essentially, the Office is asserting that Applicant's claims are too broad because the specific amounts have not been claimed for what amount of botulinum toxin is less than the amount used to paralyze a muscle. However, the case law is clear that breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971).

Further, when the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. MPEP § 2173.02 (Emphasis in original). Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. *Id.* Further, Applicant reminds the Office, in addition to the reference to the MPEP given above, that "the examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 USC 112, second paragraph, is whether the claim meets with threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available." MPEP § 2173.02.

In view of the foregoing, Applicant respectfully requests the Office to withdraw the rejection of claims 1-6, 8-10 and 12-27 under 35 USC § 112, ¶2.

CONCLUSION

The Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207. Should any issues remain, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Dated: 21 October 2008

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